

**Commonwealth of Massachusetts  
Betsy Lehman Center for Patient Safety and Medical Error Reduction  
Expert Panel on Weight Loss Surgery**

**Executive Report**

**August 4, 2004**

**(PREPUBLICATION COPY)**

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## **MISSION STATEMENT**

The Expert Panel has convened under the auspices of the Betsy Lehman Center for Patient Safety and Medical Error Reduction to make evidence-based recommendations to the Lehman Center for improving the safety and well-being of patients who undergo weight loss surgery in the Commonwealth of Massachusetts.

Toward that end, we reviewed weight loss surgical procedures; analyzed the current medical literature; identified safety issues; recommended specific steps to improve patient safety and reduce the risk of medical errors; identified best practices and clinical guidelines; identified directions for future research; and provided recommendations for credentialing and training improvements.

Our goal is a system-based approach to advance patient care across the Commonwealth based on the medical literature; to reduce unnecessary variability; and improve surgical and patient outcomes.

## FOREWORD

Obesity has reached epidemic proportions in the United States. It is well-established that obesity substantially raises risk of morbidity and mortality. Recently, the federal Medicare program announced a policy change which may allow millions of Americans with obesity to make medical claims for treatments and therapies for obesity. Of the many patient safety issues associated with obesity treatments, weight loss surgeries have emerged as a focal point in Massachusetts.

Established in January 2004, the Betsy Lehman Center for Patient Safety and Medical Error Reduction (Lehman Center) assists health care professionals, facilities, agencies, and the general public with practices and procedures that promote the highest standards for patient safety in the Commonwealth.

In February 2004, Christine Ferguson, the Commissioner of Public Health, requested that the Lehman Center convene an Expert Panel to study weight loss surgical programs and procedures as they directly relate to patient safety. After consulting with its stakeholders, the Massachusetts Coalition for the Prevention of Medical Errors (its advisory committee), and sites performing weight loss surgeries in the state, the Lehman Center convened a 24-member Expert Panel. It included a consumer representative and leading authorities in the fields of obesity treatment, patient safety, nutrition, medical practice, managed care, pediatrics, nursing, and ethics.

The expert panel used a state-of-the-art model of evidence-based medicine to make best practice recommendations. This is the first time an Expert Panel has carried out a comprehensive, in-depth, and systematic review of the entire medical literature related to weight loss surgeries. These recommendations will have far-reaching clinical and public health implications not only for the Commonwealth, but nationwide.

What follows is an extraordinarily comprehensive report from the Expert Panel to the Lehman Center. More than 80 of the Commonwealth's obesity experts and health care professionals collaborated on it. My hope is that it will define the credentials, tools, and procedures required to make best practice the only practice in the care of weight loss surgery patients. Equally important, I hope that this report will enhance public health policies and scientific research in the area of weight loss surgery. Our ultimate goal is to optimize patient safety and promote high quality care.

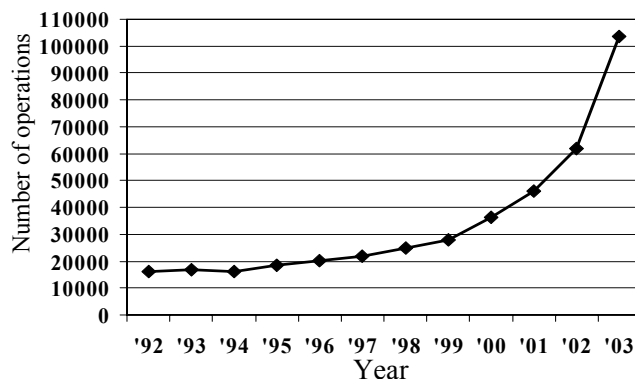
I want to express my deepest gratitude to all Expert Panel and task group members for their tireless efforts and enormous dedication to this project. I especially want to thank the chair, Dr. Alan Harvey and vice chair, Dr. George Blackburn, and our clinical epidemiologist, Dr. Frank Hu, for their leadership and commitment to this project. Last but not least, I want to thank DPH and Lehman Center staff, especially our project manager, Lori Bassinger, and our medical librarian, Elizabeth Fitzpayne, for their hard work in coordinating and facilitating this project.

Nancy Ridley, M.S., Director  
Betsy Lehman Center for Patient Safety and Medical Error Reduction

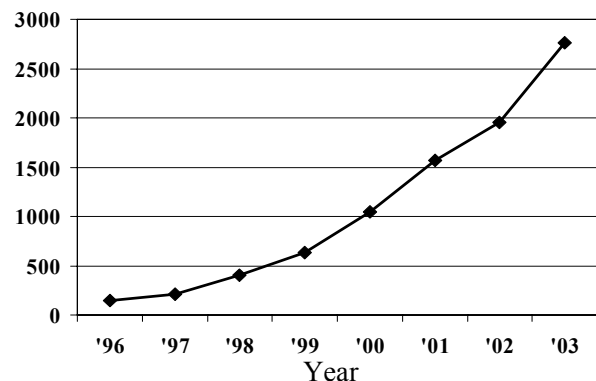
## PREFACE

Obesity exacts a devastating personal and economic toll on those who suffer from it. Few are unaware of its impact on health, or its growing prevalence. The number of obese adults in the U.S. doubled to around 63 million between 1976-1980 and 2001-2002. The ranks of those with severe obesity, who are more than 100 lbs overweight, grew at an even faster rate—to nearly 11 million people in 2001-2002.

The rapid spread of severe obesity, combined with lack of adequately effective dietary and pharmacological treatments, has fueled demand for weight loss surgery (WLS), and greatly increased the number of operations performed (see Figure). Between the early 1990s and 2003, WLS nationwide rose from around 16,000 to over 100,000 a year. Continued growth is expected, with more than 140,000 procedures anticipated for 2004. In Massachusetts alone, more than 2,700 gastric bypass operations were carried out in 2003 compared with fewer than 150 in 1996.



Estimated number of WLS operations  
performed in the U.S., 1992-2003  
(*NEJM*, 2004;350:1076)



The number of WLS operations  
performed in Massachusetts, 1996-2003  
(*Dept. of Public Health*)

This dramatic growth has raised concern about the safe practice of WLS within the Commonwealth of Massachusetts, and nationwide, and has prompted the Betsy Lehman Center to form the Expert Panel on WLS to assess patient safety issues in weight loss programs and procedures.

Surgical obesity treatment involving gastric restrictive procedures started in Massachusetts more than 30 years ago at the Deaconess Hospital, which was affiliated with Harvard Medical School and the Department of Nutrition and Food Science at MIT. At that time, research and training were coordinated by the hospital's nutrition support service. They were multidisciplinary and comprehensive, inpatient and outpatient, state-of-the-art—informed by in-depth research into every aspect of severe obesity (medical, clinical, surgical, nutritional, metabolic, endocrine, pediatric, and basic and clinical research and training) at the time.

Since the 1970s, experience and technology have changed the field of WLS, and market forces have expanded it with new practitioners. Some procedures have evolved, while others have

become obsolete. The newest developments are in minimally invasive surgery, or laparoscopy. Gastric bypass surgeons are already working in this area, bringing new techniques to a well-established approach.

WLS is an effective treatment for severe, medically complicated and refractory obesity; the only proven way to achieve significant long-term weight loss, improve obesity-related comorbidities, reduce the risk of premature death, and improve quality of life in a large percent of treated individuals. It is also life-altering major surgery, with all its attendant risks. This panel has been formed to identify those risks, and minimize them in pursuit of patient safety.

The panel and its task groups include 80% of the sites performing WLS in the Commonwealth; together, they cover most of the state. By including so many facilities and practitioners, and by openly sharing this report with all centers performing these procedures, we have established a network for information sharing, benchmarking, and continued improvements in the care of severely obese patients. This report from the Lehman Center, developed using a process based on the published medical literature and expert opinion, will define best practices in WLS, and set the standard for excellence. It will be applicable to all patients, in the Commonwealth of Massachusetts, and beyond.

Because of the rapid growth and development of WLS and related technologies, we recommend establishment of a continuing committee to advise the Department of Public Health in this area to facilitate communications with institutions, programs, centers and providers contributing to the care of WLS patients; to provide recommendations to DPH and other parties related to implementation of recommendations of the Expert Panel; and to examine emerging issues, such as those related to data collection, risk adjustment and new WLS-related technologies. Undoubtedly, continued efforts are needed to achieve our goal of delivering the safest possible care to patients with obesity.

Alan M. Harvey, M.D., M.B.A.  
Chair

George L. Blackburn, M.D., Ph.D.  
Vice Chair

## BACKGROUND

### Obesity Epidemic

Obesity is a growing epidemic in the United States. According to the Centers for Disease Control and Prevention (CDC), the prevalence of adult obesity (Classes I and II; see Table 1) rose nearly 50% in the period between 1976-1980 and 2001-2002, when an estimated 63 million people had obesity. Severe (Class III) obesity grew at an even faster rate—nearly 4-fold between 1986 and 2000. In 2001-2002, some 11 million individuals had severe obesity, or were more than 100 lbs overweight. Among adolescents 12 to 19 years old, approximately 16% were overweight (defined as at or above the 95th percentile of the sex-specific BMI for age growth charts) in 1999-2002, an increase of nearly 50% over the previous decade. Approximately 60% of these overweight adolescents will have obesity as adults.

**Table 1. Classification of Obesity**

	<b><u>Obesity Class</u></b>	<b><u>BMI (kg/m<sup>2</sup>)</u></b>
Underweight	---	<18.5
Normal	---	18.5-24.9
Overweight	---	25.0-29.9
Mild Obesity	I	30.0-34.9
Moderate Obesity	II	35.0-39.9
Severe Obesity	III	≥40.0

Body Mass Index (BMI) is the standard measure to define obesity. BMI is calculated as weight [kg]/height squared [m<sup>2</sup>]. To calculate BMI using pounds and inches, use: weight [lbs] x 703/height squared [inches<sup>2</sup>]. Weight class is determined by BMI cutpoints. Obesity is diagnosed at BMI ≥30 kg/m<sup>2</sup>

Obesity costs the U.S. economy in excess of \$100 billion a year. It confers substantially increased risk of morbidity and all-cause mortality from type 2 diabetes, hypertension, dyslipidemia, cardiovascular disease, stroke, sleep apnea and other respiratory problems, gallbladder disease, fatty liver disease, osteoarthritis, and several forms of cancer. In 2000, obesity-related diseases were responsible for 400,000 deaths. In addition to adverse health effects, people with obesity also suffer substantial social stigmatization and workplace discrimination.

### A Primer on Weight Loss Surgery (WLS)

Several types of WLS procedures are performed today. Health insurance policies cover many of them based on a finding from the 1991 NIH Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity that surgery is an appropriate treatment for patients with Class III obesity, or with Class II obesity and major comorbidities. The members of the 1991 Conference recommended vertical banded gastroplasty (VBG) or Roux-en-Y gastric bypass



(RYGB). Since then, VBG has been displaced by RYGB and newer laparoscopic approaches. The laparoscopic adjustable gastric band (LAGB), introduced to the U.S. market in 2001, has become increasingly popular. At present, RYGB and LAGB are the gastrointestinal WLS operations most commonly performed in the U.S..

### Roux-en-Y Gastric Bypass

RYGB is the gold standard WLS in the U.S. today, and the most frequently performed. It involves creating a small stomach pouch and rerouting a portion of the alimentary tract to bypass the distal stomach and proximal small bowel. Proven benefits of RYGB include significant, long-term weight loss and improvement or resolution of many obesity-related comorbidities. Its risks include infrequent but serious surgical complications (e.g., pulmonary embolism, intestinal leak, wound infection, and staple line failure); long-term deficiencies of iron, calcium, vitamin B12 and vitamin D; and the possibility of weight regain.

### Laparoscopic WLS

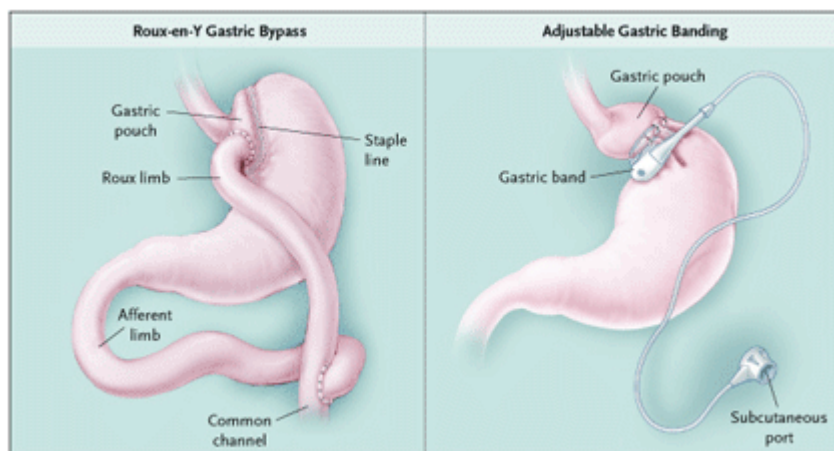
Weight loss surgeons have developed laparoscopic approaches to gastric bypass and other WLS procedures. Like open procedures, laparoscopic WLS has proven effective at producing significant and sustained weight loss, along with improvements in comorbid conditions and quality of life. Because it is less invasive than open surgery, it also shortens recovery time.

Laparoscopic surgeons gain access to the abdomen via several small incisions. They insert a tiny video camera through one of the incisions, and surgical instruments through the others. They operate by watching their work on a large-screen monitor. Laparoscopic techniques for WLS are difficult and associated with a longer and steeper learning curve than equivalent open procedures.

### Laparoscopic Adjustable Gastric Banding (LAGB)

In LAGB, an adjustable silicone band is placed around the upper stomach to create a small pouch and a restricted outlet. The diameter of the outlet can be changed by injecting or removing saline through a portal under the skin. If it is not effective, or if serious complications develop, the band can be removed.

Though a large body of evidence, especially from European studies, suggests that LAGB is effective and safe for weight loss, long-term data from U.S. patients are still limited. Available studies demonstrate variable benefit, and the basis of this variation remains unclear. Complications from gastric banding include band migration or erosion, gastroesophageal reflux disease (GERD), esophagitis, and problems with the subcutaneous port or tubing.



**Figure 1. Commonly used weight loss surgery procedures**

The left panel shows a Roux-en-Y gastric bypass, in which a small proximal gastric pouch is connected to a Y-shaped loop of the small bowel. The proximal stomach pouch is separated from the large, distal stomach with several rows of staples. The right panel shows a gastric banding procedure. The band, which can be adjusted by the infusion of saline, is placed around the stomach near its upper end, creating a small pouch and a restricted passage to the larger remaining part of the stomach. In both procedures, the gastric pouch is generally less than 30 ml.

Steinbrook R. Surgery for severe obesity. *New England Journal of Medicine*. 2004; 350:1075-1079

Mun, EC, Blackburn, GL, Matthews JB. Current status of medical and surgical therapy for obesity. *Gastroenterology*. 2001;120:669-681

## Framework for evidence-based recommendations

The 24-member Expert Panel was divided into nine task groups:

- Surgical care
- Criteria for patient selection and multidisciplinary (psychological, nutritional, medical) evaluation and treatment;
- Patient education/informed consent;
- Anesthetic perioperative care and pain management;
- Nursing perioperative care;
- Pediatric/adolescent care;
- Facility and QA/QI (quality assurance/quality improvement) resources;
- Coding and reimbursement;
- Data collection (registries)/future considerations.

Panel members joined one or two task groups, each with an assigned coordinator. In developing recommendations, they were asked to focus on five topics: patient safety; medical errors; credentialing; systems improvements; and research needed for the future.

Recommendations were based on evidence from systematic reviews of literature published in MEDLINE between January 1980 and April 2004 (Some groups have searched other databases or focused on more recent literature); searches were carried out by an expert in library science, aided by a clinical epidemiologist with experience in systematic reviews (Appendix I). Task groups used a data extraction sheet (Appendix II) to mine relevant information from key studies. To grade the quality of evidence, the panel developed a classification system based on models used by the U.S. Preventive Services Task Force and other respected organizations and government agencies (see Table 2).

The panel's recommendations are based on the best available evidence, including randomized controlled trials (RCTs), observational studies, and expert opinions. RCTs are considered the highest-level evidence of clinical safety and efficacy, but there are few such studies available on WLS.

The panel met six times between February and July, 2004. There were also several task group meetings, and numerous telephone conferences and e-mail communications. The core group, composed of the panel chairs and Department of Public Health personnel, met five times. Members from the Massachusetts Coalition for the Prevention of Medical Errors participated in two Expert Panel meetings.

Each task group prepared a critical summary of its literature review, and developed recommendations based on the best available evidence (Individual scientific reports are compiled in a separate document). This Executive Report (A summary of key recommendations from all task groups) was approved by the panel at its last meeting on July 19, 2004.

**Table 2. Grading System for Evidence-Based Recommendations**

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Category A	Evidence obtained from at least one well-conducted randomized clinical trial or a systematic review of all relevant RCTs
Category B	Evidence from well-conducted prospective cohort studies, registry or meta-analysis of cohort studies, or population-based case-control studies
Category C	Evidence obtained from uncontrolled or poorly controlled clinical trials, or retrospective case-control analyses, cross-sectional studies, case series, or case reports
Category D	Evidence consisting of opinion from expert panels or the clinical experience of acknowledged authorities

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Adapted from the criteria used by the U.S. Preventive Services Task Force (USPSTF) and American Diabetes Association.

## SUMMARY OF EVIDENCE-BASED RECOMMENDATIONS

### I. SURGICAL CARE

The Surgical Care Task Group identified more than 100 papers, but only the 26 most relevant studies were reviewed in detail. It also relied on literature from the 2003 Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Appropriateness Conference that included a review of some 50 studies and a summary of the state-of-the-art in open and laparoscopic WLS operations.

#### A. Patient Safety

##### 1. Risks

The complications of commonly performed WLS procedures are well defined (Category B evidence). They include:

##### Roux-en-Y Gastric Bypass (% of patients)

Deep vein thrombophlebitis	1-2%
Pulmonary embolus	0.5%
Splenectomy	1%
Gastrointestinal leak	1-3%
Postoperative bleeding	1-5%
Stomal obstruction	5-15%
Small bowel obstruction	1-3%
Mortality (within 30 days)	0.5–1%
Protein-calorie malnutrition	<1%

##### Laparoscopic Adjustable Gastric Band (% of patients)

Injury to adjacent organs	0.5%
Band erosion	1%
Band slippage/stomach herniation	2-3%
Port infection	1%
Mortality (within 30 days)	<0.5%

The revision rate for LAGB patients may be as high as 10%; such operations are performed to replace the port and/or tubing, and possibly, to replace, reposition, or remove the band.

#### B. Types of Weight Loss Surgery

A large body of evidence suggests that commonly performed WLS procedures, such as RYGB, are effective in producing long-term weight loss, improved quality of life and health outcomes, and reduced mortality (Category B).

This task group recommends use of the SAGES Appropriateness Conference statement in selecting types of WLS. Evidence below reflects the panel's statements on the Appropriateness Conference, and the consensus of task group members.

## **1. Gastric Bypass**

### **Roux-en-Y Gastric Bypass (open and laparoscopic)**

Roux-en-Y gastric bypass (RYGB) produces greater long-term weight loss than gastric partitioning alone or vertical banded gastroplasty (VBG) (Categories A and B), and it is substantially safer than jejunoileal bypass.

Open and laparoscopic RYGB produce similar short-term weight loss and improvements in comorbid medical conditions. The laparoscopic approach improves short-term recovery from surgery, and has a lower incidence of incisional hernias than the open RYGB (Long-term data are not yet available) (Categories A and B).

Laparoscopic RYGB has become increasingly common, but it needs to be performed by appropriately trained, qualified, laparoscopic weight loss surgeons (Category D).

Long limb (>150 cm) RYGB may produce superior short-term weight loss in patients who are more than 200 lbs overweight, or have BMI  $\geq 50$ . Optimal limb length is unknown, but long-term follow-up indicates that the benefit of longer limb length decreases over time and may disappear completely (Category C).

## **2. Malabsorptive Procedures**

### **Biliopancreatic Diversion with Duodenal Switch**

Bileopancreatic diversion with or without duodenal switch is effective in producing weight loss (These procedures are still considered investigational, however, due to limited data on long-term safety and metabolic side effects) (Category C).

## **3. Restrictive Procedures**

### **Laparoscopic Adjustable Gastric Band (LAGB)**

LAGB produces variable short-term weight loss and improvements in obesity-related comorbidities (Category B). It has lower average mortality rates than RYGB or malabsorptive procedures (Categories B and C).

Placement of the LABG in the pars flaccida path rather than the retrogastric position may reduce the incidence of postoperative complications (Category C).

### **Vertical Banded Gastroplasty (VBG)**

The role of VBG in the treatment of patients with severe obesity is limited (Category D). This procedure has been largely supplanted by LAGB.

### **C. Strategies for Medical Error Reduction**

Risk of medical errors and complications are most likely to be minimized under the following conditions (Category D, unless otherwise noted):

- Rigorous training that puts a strong emphasis on patient safety and includes close monitoring and early supervision of surgeons in their learning curves.
- Ongoing training and accumulation of experience that takes place in a supportive setting, with extended proctoring by experienced weight loss surgeons.
- High-volume surgeons (50-100 cases per year) operating in properly equipped, high-volume weight loss centers (>100 cases per year) with integrated and multidisciplinary treatment. High-volume surgeons tend to have better short-term outcomes (Category B).

### **D. Credentialing of Systems and Practitioners**

The followings are proposed guidelines for credentialing of WLS facilities and surgeons:

#### **Facilities**

Facilities should meet the following criteria for WLS credentialing (also see Facility Resources and QA/QI recommendations):

- System-wide environment (e.g., pretesting, recovery, ICU, diagnostics) that is appropriately designed and properly equipped for the comfort and care of WLS patients
- Designated, recognized, and well-supported anesthesiology and operating room teams for WLS
- Designated, recognized, and well-supported inpatient facilities for the care and treatment of WLS patients
- Allocation of anesthesiology and critical care resources for 24/7 coverage of WLS patients by attending-level staff
- On-site (if needed) specialists to educate, evaluate, and manage WLS patients

## **Surgeons**

The Expert Panel recommends that WLS privileges be divided into full and provisional and that there be separate credentialing criteria for open and/or laparoscopic procedures. For all WLS procedures, proposed criteria require that surgeons be board-certified or board-eligible. We recommend review of privileges every two years. These recommendations are based on Category D evidence, unless otherwise noted.

### **1. Establishment of Provisional Privileges (open WLS procedures)**

- Completion of the (ASBS) American Society for Bariatric Surgeons essentials courses or equivalent
- Successful completion of 10 open cases proctored by a surgeon with full privileges for open WLS.

#### **1a. Establishment of Provisional Privileges (laparoscopic WLS procedures other than LAGB)**

- Meets requirements for provisional open privileges
- Successful completion of 25 laparoscopic cases proctored by a surgeon with full privileges for laparoscopic WLS (Category B).

### **2. Establishment of Full Privileges (open or laparoscopic WLS procedures)**

- Review of first 15 independently performed cases by a committee that includes the chief of surgery at the surgeon's institution and an experienced (>100 cases) weight loss surgeon; this committee may also include members of the institution's Quality Assurance and Credentialing programs
- No substantial deviation in risk-adjusted outcomes from accepted norms and benchmarks.\*

\* Substantial deviation but no threat to patient safety – consider continuation of provisional status

\* Substantial deviation with actual or potential threat to patient safety – revoke provisional status, allowing reapplication

#### **2a. Recredentialing of Full Privileges (open or laparoscopic WLS procedures)**

- Maintenance of board certification or board eligibility. Credentialed gastrointestinal surgeons who are active staff member with full admitting privilege at facility obtaining bariatric privilege are eligible
- 100 primary or revisional WLS procedures within the previous 2 years (Categories B and D)
- Presence of a second weight loss surgeon on staff with either full or provisional privileges within the same program
- Established program for long-term ( $\geq 5$  years) patient follow up

- Capacity to maintain an electronic database including short- and long-term patient outcomes
- No substantial deviation in risk-adjusted outcomes of WLS from accepted norms or benchmarks
- At least 12 weight loss surgery CME credits from appropriately accredited bariatric surgery society meetings (e.g., ASBS, International Federation for the Surgery of Obesity-IFSO); obesity-related sections of accredited general surgery meetings (e.g., SAGES, Society for Surgery of the Alimentary Tract-SSAT, American College of Surgeons-ACS); or other accredited courses focusing on obesity.

### **3. Other Privileges (including revisional surgery, LAGB, and emerging technologies)**

- Pursuit after conclusion of provisional period
- Full privileges for the route consistent with the technology or revision required (e.g., LAGB performed by a surgeon with full laparoscopic WLS privileges and practical training in the specific technology)
- Approval by Institutional Review Board for investigational open, laparoscopic, endoscopic, or percutaneous weight loss interventions
- Principal investigator (PI) or co-investigator who is a weight loss surgeon with appropriate privileges and training consistent with the technology
- Development and testing of emerging technology should be conducted by a multidisciplinary team in accordance with the guidelines recommended by the Expert Panel.

### **E. Research Needed for the Future**

- Studies to standardize the technical aspects of WLS
- Prospective, randomized, controlled trials to compare the efficacy and safety of malabsorptive and gastric bypass procedures.



## **II. CRITERIA FOR PATIENT SELECTION AND MULTIDISCIPLINARY (PSYCHOLOGICAL, NUTRITIONAL, MEDICAL) EVALUATION AND TREATMENT**

The Multidisciplinary Care Task Group identified more than 3,000 abstracts related to WLS in general, and to nutrition, medical, and psychological care in particular; 104 of these studies were reviewed in detail.

### **A. Patient Safety**

#### **1. Criteria for Patient Selection**

The Expert Panel recommends use of patient selection guidelines from the 1991 National Institutes of Health (NIH) Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity. These criteria, paraphrased below, include:

- BMI  $\geq 40$  kg/m<sup>2</sup>, or BMI  $\geq 35$  kg/m<sup>2</sup> in association with major medical complications of obesity (e.g., cardiovascular disease, type 2 diabetes, sleep apnea)
- A well-informed and motivated patient
- A strong desire for substantial weight loss
- Failure of other non-surgical approaches to long-term weight loss
- Acceptable operative risks.

Most patients with severe obesity are unlikely to achieve and maintain a healthy weight with non-surgical treatment (Category A). We were unable to recommend specific criteria for demonstrating prior, unsuccessful efforts at long-term weight loss via non-surgical means (Category D).

Increased risk of complications: The risk of complications and mortality is greater with revisional surgery, increased weight or BMI, male gender, and increased age. In particular, patients older than 50 years, with a BMI  $> 50$  kg/m<sup>2</sup> appear to have a significantly elevated risk (Category B). Severe medical conditions that may contribute to increased risk include type 2 diabetes, hypertension, and obstructive sleep apnea (Category C). Use of hospitals with qualified 24-hour, in-house coverage for airway and resuscitative management should be considered for such patients (Category D).

#### **2. Multidisciplinary Care**

The Expert Panel strongly recommends preoperative and postoperative medical, nutritional and behavioral/psychological care for WLS patients. Recommendations in each area are listed below,

along with the categories of supporting evidence. Preferred providers are those who specialize in, or have substantial experience with, the care of WLS patients (Category D).

### **Behavioral/Psychological Care**

Evaluation by a credentialed expert in psychology and behavior change, preferably a psychiatrist, psychologist, or social worker. He or she must be skilled at identifying psychological contraindications to WLS and potential barriers to success (e.g., inability to make needed behavior changes). They must be able to develop plans and implement treatments to address these barriers (Category D).

### **Nutritional Care**

Preoperative education and counseling by a registered dietitian, with a well-defined diet progression after surgery. Early postoperative priority should be placed on maintenance of adequate hydration and protein intake (Category D). Blood levels of micronutrients should be assessed for deficiencies prior to surgery, 6 months after surgery, and at least annually thereafter (Category D). All patients should take a daily multivitamin (Category A) and calcium supplement with added vitamin D (Category D). Thiamine supplementation should be considered for patients with persistent vomiting or poor intake (Category C). Prenatal multivitamins are an option for patients at risk of deficiencies in iron and/or folic acid. Regular use of additional iron supplements is also likely to minimize iron deficiency in at-risk patients (Category A). Patients who have had RYGB or malabsorptive procedures should be considered at risk for metabolic bone disease, and patients who have additional risk factors for metabolic bone disease should be assessed periodically after WLS (Category A).

### **Medical Care**

Physicians and non-physician providers (e.g., nurses and physicians assistants) provide unique contributions to patient care; all should be considered important members of the multidisciplinary WLS treatment team. Extreme obesity is associated with several conditions known or suspected to increase operative risk. The followings are recommendations for assessment and treatment for specific conditions:

Obstructive sleep apnea (witnessed or daytime symptoms): Preoperative assessment of patients with signs or symptoms of sleep apnea (e.g., increased neck circumference, daytime sleepiness or other symptoms), as well as patients with hypertension, lower extremity edema, or cardiac dysfunction. There are insufficient data to recommend specific perioperative measures, although oxygen saturation monitoring appears prudent (Category D).

Deep vein thrombosis/pulmonary embolism (DVT/PE): WLS patients are at high risk for venous thromboembolism (VTE) and should receive perioperative DVT/PE prophylaxis. Except where contraindicated, prophylaxis should be carried out via combined use of mechanical methods and anticoagulant strategies (Categories A and B). Patients at particularly high risk for DVT/PE should be considered for preoperative inferior vena cava filter placement (Category D).

Liver disease: Patients with unexplained elevations of hepatic transaminases should undergo preoperative evaluation for common etiologies of liver disease. Patients with preoperative or intraoperative evidence of fibrosis, cirrhosis or hepatic dysfunction should undergo intraoperative liver biopsy. Those with evidence of insulin resistance should also be considered for intraoperative liver biopsy. In cases where cirrhosis is found, decisions on whether to proceed with WLS should be made on a case-by-case basis; factors to consider include the overall health of the patient, the presence of gastric or intestinal varices or ascites, and the physical or histologic appearance of the liver (Category B).

Smoking cessation: All patients who smoke cigarettes should be encouraged to quit, preferably at least 6-8 weeks prior to surgery (Category D). Use of nicotine replacements and/or bupropion may help minimize weight gain with smoking cessation. To reduce long-term health effects from smoking, patients should not resume tobacco use after surgery (Category A).

Preoperative weight loss: All patients should be encouraged to lose weight prior to surgery (Category D). Those with BMI > 50 or comorbidities such as sleep apnea, type 2 diabetes, glucose intolerance, and hypertension should attempt to lose 5-10% of initial weight. Some patients (e.g., those already maintaining significant losses or taking medications that promote weight gain), may be unable to reduce weight prior to surgery. Decisions on whether to proceed with surgery in these patients should be made on a case-by-case basis given the limited data linking preoperative weight loss to safety or efficacy outcomes (Categories C and D).

Coronary Artery Disease (CAD): WLS patients with known or suspected CAD should receive perioperative beta blockers to reduce cardiovascular complications (Category D). Current guidelines from the American College of Cardiology and the American Heart Association recommend use of beta blockers prior to, during, and after surgery in patients with a history of coronary artery disease (CAD), or with two or more CAD risk factors such as hypertension or high cholesterol (if use is not contraindicated).

## **B. Strategies for Medical Error Reduction**

Contraindications to WLS include unstable CAD, severe pulmonary disease, portal hypertension with gastric or intestinal varices, and other conditions thought to seriously compromise anesthesia or wound healing risk (Category D).

Contraindications to WLS include inability to comprehend basic principles of the procedure or to follow basic postoperative instructions (Category D).

Patient care should be coordinated by regular meetings of the multidisciplinary team. In centers where this is not possible, specific procedures should be established to insure timely communication of patient care information among participating providers (Category D).

## **C. Systems Improvements**

Weight loss outcome after WLS should be measured as change in BMI or percent excess body weight loss (Categories C and D).

## **D. Credentialing**

Nutritional care should be provided by registered dietitians or physicians with specialty training in nutrition medicine (Category D).

## **E. Research Needed for the Future**

- Prospective studies (with standardized definitions of preoperative variables and postoperative endpoints) to better define selection criteria, and predict complications and outcomes
- Studies examining the long-term effect of WLS on weight loss, complications and other outcomes
- Studies to identify better methods for systematically assessing outcomes other than weight change or BMI, e.g., long-term effects on health and quality of life
- Studies to determine the effects of various preoperative and postoperative practices on outcomes after WLS.

### **III. PATIENT EDUCATION / INFORMED CONSENT**

We found no empirical data on the informed consent process for WLS. Recommendations are based on three review articles, materials from six Massachusetts WLS programs, discussions with WLS program leaders, and the consensus of task group members (Evidence Category D).

#### **A. Patient Safety**

##### **1. Understanding vs. disclosure**

The informed consent process can make a significant contribution to patient safety and long-term outcomes. It should include an assessment of the patient's understanding of the content of the informed consent. Informed consent based on comprehension (vs. just disclosure) better promotes patient safety.

##### **2. Educational objectives**

Educational objectives of the informed consent process include:

- Maximize participation in preoperative program by the patient
- Helping patients make informed decisions about surgery
- Improving each patient's short- and long-term health and well-being.

##### **3. Appropriate content**

WLS programs should include information on the following topics as part of their informed consent process:

- Health risks associated with obesity
- Alternatives to WLS for treatment of obesity
- Alternative forms of WLS, and our current understanding of their respective risks and benefits.
- Potential complications in the postoperative period and beyond
- Pre-surgical Strategies to reduce surgical risks, including preoperative weight loss when possible
- Potential impact of WLS on family, friends, and relationships
- Common psychological adjustment issues after WLS
- Postsurgical requirements, especially those related to diet and medications
- Aftercare programs and sources of support.

##### **4. Teaching and learning**

WLS programs should use active teaching and learning techniques that may include:

- Videotapes that prospective patients can take home and share with their family and friends

- Participation of patient's support network (family or friends) in education programs and discussions with the WLS clinical team
- Practice with a mock post-surgical diet regimen to improve understanding of long-term implications.

## **5. Assessment of learning**

Assessment of learning should be an integral part of the informed consent process. Some programs have used diet preparation and documentation exercises, oral or written tests and tools to evaluate the effectiveness of their education programs.

## **6. Promoting realistic expectations**

It is important emphasize that surgery is only one component of a lifetime weight management program. An "agreement," signed by the patient and a member of the clinical team, may be helpful in reinforcing the patient's commitment to long-term follow up and self-management. The "agreement" is not legally binding.

## **D. Research Needs for the Future**

- Studies to assess the effect of different forms of education on levels of patient understanding
- Studies to assess patient satisfaction with different informed consent processes
- Operations research to increase the efficiency and reliability of the informed consent process.

To facilitate improvements in patient education and informed consent, the Expert Panel recommends the development and maintenance of a public repository of educational materials and informed consent documents used by Massachusetts WLS programs that is made fully available to the public.

## **IV. ANESTHETIC PERIOPERATIVE CARE AND PAIN MANAGEMENT**

The anesthesia task group's literature search identified 195 scientific abstracts, 35 of which were reviewed in detail. An additional 10 references provided general information or indirectly-related trial results (all Category D for final patient outcomes in relation to the 5 issues under consideration).

### **A. Patient Safety**

#### **1. Preanesthesia evaluation**

At least one day before scheduled WLS, an anesthesia clinician should conduct a preanesthesia evaluation. Each patient should be clinically evaluated for, and specifically asked about, signs and symptoms of sleep apnea. Baseline routine laboratory testing within 6 months of WLS should include hematocrit, glucose, creatinine, and BUN.

#### **2. Anesthesia induction and emergence**

The 30° reverse Trendelenburg (head up) position—with additional upper body and airway positioning measures as needed to facilitate successful tracheal intubation—is recommended for routine use. Unless medically contraindicated, this anesthesia induction positioning helps to minimize the apneic (non-breathing) period and possibly the risk of aspiration.

#### **3. Equipment and personnel**

The anesthesia practitioner should be proficient in the use of a variety of alternative airway management devices and techniques; these should be immediately available to him or her during induction of anesthesia. An additional anesthesia practitioner, the operating surgeon, and an operating room nurse should be immediately available to the anesthesia care team during induction of, and emergence from, anesthesia.

#### **4. Dosing of medication**

Proper dosing of medications for patients with severe obesity is uncertain. The task group recommends that clinicians should begin with doses close to the estimated lean body mass (approximately 120% of ideal body weight), and be adjusted as needed.

#### **5. Intraoperative monitoring**

In addition to standard American Society of Anesthesiologists (ASA) intraoperative monitoring protocols (including an electrocardiogram, blood pressure, oxygen saturation, inspired oxygen concentration, and end-tidal carbon dioxide values), assessment of body temperature is recommended during WLS. Use of alternate sites for noninvasive blood pressure measurements (e.g., the forearm) should be considered as needed. Invasive hemodynamic measurements should be used as medically indicated.

## **6. Postanesthesia care**

The *ASA Standards for Postanesthesia Care* should be followed in accordance with the patient's overall medical condition and the presence or absence of sleep apnea. CPAP/BiPAP should be available to patients as needed for noninvasive positive pressure ventilation.

## **7. Postoperative pain management**

Major postoperative pain treatment strategies include: thoracic epidural analgesia (TEA), and patient controlled intravenous analgesia (PCA).

When TEA is preferred, we recommend a combination of local anesthetics with opioids (narcotics), with or without epinephrine in the epidural solution, unless any of these agents is specifically contraindicated. Standardized nursing protocols should be established for monitoring, maintaining, and troubleshooting epidural management daily, and an acute pain service should be available to provide assistance or oversight as needed. TEA is not typically needed following laparoscopic procedures.

When PCA management is preferred, the combination of an opioid-based PCA with local anesthetic wound infiltration and adjunct (non-narcotic) analgesic medications is recommended, unless any of these agents is specifically contraindicated. The routine use of a continuous opioid background infusion PCA mode should be avoided.

## **B. Strategies for Medical Error Reduction and Systems Improvement**

### **1. Effective communication**

Effective and unimpaired intraoperative and perioperative communication between the anesthesia and surgical members of the WLS care team is essential to promote patient safety.

### **2. Equipment and skills**

Throughout the perioperative period, at least one portable storage unit with specialized equipment for difficult airway management should be readily available; it should be maintained and operated by anesthesia clinicians. A clinician with advanced airway management skills should be immediately available.



### **3. Patient monitoring**

Patients with documented or suspected sleep apnea may require continued close perioperative monitoring to protect against respiratory depression beyond the recovery room; we encourage the formulation of, and adherence to, institutional protocols of continued close monitoring as clinically indicated. A national task force from the American Society of Anesthesiologists (ASA) is currently developing recommendations for the perioperative care of patients with sleep apnea. These should be followed when they become available.

## **C. Credentialing Needs**

### **1. Accredited residency program**

An anesthesia residency program accredited by the Accreditation Council for Graduate Medical Education (ACGME) provides extensive experience in the anesthetic and perioperative care of patients with severe obesity undergoing WLS and other surgical procedures. No specific recommendations for additional credentialing of anesthesia practitioners or systems can be made at this time.

### **2. Interdepartmental liaison**

Ongoing communication among anesthesiologists, surgeons and other members of the WLS team facilitate discussion of patient care issues and the exchange of scientific information. An anesthesia clinician with a special interest in anesthetic care and pain management for WLS patients should be identified to serve as an interdepartmental liaison.

## **D. Research Needed for the Future**

- Studies of patient safety and outcomes
- Pharmacokinetic and pharmacodynamic studies of anesthetics, analgesics, and other perioperative medications to define safe, effective and accurate dosing schedules in patients undergoing WLS
- Studies of reduced-opioid or non-opioid-based pain management strategies
- Development of an evidence-based algorithm for preoperative evaluation of patients undergoing WLS
- Development of evidence-based algorithms for risk stratification and perioperative patient
- Studies of the impact of sleep-disordered breathing syndromes (e.g., obstructive sleep apnea) and perioperative care for these disorders on outcomes after WLS
- Development of accurate and well-tolerated monitoring devices for physiological parameters (including blood pressure) particularly suited for use in WLS patients.

## **V. NURSING PERIOPERATIVE CARE**

A systematic review of MEDLINE, nursing journals, and the CINAHL® database for nursing and allied health literature identified 134 articles; 16 of them were relevant to this report. Recommendations are based on published evidence and the consensus of task group members (Category D).

### **A. Patient Safety**

#### **1. Education**

Nursing care is a critical factor to ensure patient safety in WLS. Those who care for patients with severe obesity should complete a competency-based orientation that enables them to identify potential complications and prevent adverse outcomes. Core curriculum should cover the physiological and psychological effects of obesity, associated comorbidities, surgical options, and benefits and risks of surgery. Nurses should be able to demonstrate skill and knowledge in the use of special equipment for patients with severe obesity.

Educational in-service sessions should be available to increase understanding of obesity-related psychological issues and to promote awareness of, and minimize, intended or unintended bias (e.g., groans during transport). Nurses should take great care to ensure patient confidentiality.

#### **2. Preoperative care**

Preoperative nursing care should include a comprehensive admission assessment; identification of the patient's support system (family and/or friends); and education of the patient and family about the surgery and postoperative care.

Other responsibilities include ensuring a safe physical environment; ensuring protection of patient privacy; provision of size-appropriate materials (e.g., patient gowns) helping patients with activities of daily living, especially those made more difficult because of severe obesity, taking vital signs; checking lab work; and ensuring the completeness of paperwork. Nurses involved in the perioperative assessment should be prepared to review the planned procedure with the patient, and provide him or her with ample opportunity to ask questions. The nurse's assessment should help secure an appropriate bed designed to facilitate the recovery of patients with severe obesity.

#### **3. Operating room**

Operating room nurses should help position the patient with severe obesity properly to avoid nerve damage or other pressure-related injury. The circulating nurse must be aware of the need for extra support and should secure the patient's extremities to prevent movement or nerve plexus injuries.

#### **4. Post-anesthesia nursing**

The Post-Anesthesia Care Unit (PACU) nurse is responsible for monitoring the patient according to hospital standards of care. Additionally, the nurse must pay special attention to airway stability, hemodynamic stability, and postoperative pain management.

When any ventilated patient travels out of the PACU or ICU for testing, a respiratory therapist should accompany the nurse.

We recommend continuous oxygen saturation monitoring for patients receiving CPAP and using patient controlled analgesia (PCA).

## **5. Discharge and follow up**

Nurses should provide thorough discharge instructions, including detailed plans for follow up care. A phone call to the patient 48 hours after discharge enables nurses to clarify instructions, determine progress, provide encouragement and give patients an opportunity to ask additional questions.

## **6. Communication channels**

Communication among the nurse, surgeon and other members of the WLS care team must be open and clear.

## **7. Summary**

Safe and competent nursing care requires assessment of, and provision for, the complex physical and psychological needs of patients undergoing WLS. Potential complications that could result from obesity-related comorbid conditions call for special attention and vigilant perioperative monitoring. In addition, nurses should consistently use proper body mechanics, and take necessary precautions to avoid self-injury.

## **B. Strategies for Medical Error Reduction**

Standardized order sets and/or clinical pathways minimize medical errors. Clinical pathways, used in acute care settings to outline care plans and define expectations, also improve coordination and delivery of appropriate care.

## **C. Systems Improvements**

Use of a dedicated area, fully and appropriately equipped for the care of patients with severe obesity, will improve the quality of care, the patient's experience, and the productivity and morale of participating clinicians (The Facility and QA/QI Resources section addresses special equipment in more detail).

## **D. Credentialing of Systems and Practitioners**

At this time, there is no specific national certification for nurses who specialize in the care of patients undergoing WLS. Institutions should provide opportunities for ongoing nursing education to advance and maintain specialized knowledge in the care of these patients.

## **E. Research Needed for the Future**

Research is needed in the following areas:

- Nurses' attitudes toward patients with severe obesity
- Impact of nurses' attitudes and biases on patient outcomes and experiences
- Identification of teaching techniques that promote readiness for surgery and discharge, improved outcomes and patient safety
- Risk of injury to clinicians and others who provide care for hospitalized patients with severe obesity
- Identification of best practices to improve staff safety and prevent injury
- Identification of best practices for reduced-narcotic pain management in patients with severe obesity.

## **VI. PEDIATRIC / ADOLESCENT CARE**

The pediatric/adolescent care task group identified eight pertinent case series reports on VBG, jejunioileal bypass (JIB), LAGB, and open and laparoscopic RYGB. These papers described variable effects of WLS on short- and long-term outcomes, morbidity and mortality. In making recommendations, we supplemented the limited data with expert opinions and literature from the adult population of patients undergoing WLS (Evidence Category D).

### **A. Patient Safety**

#### **1. Eligibility**

Inclusion criteria:

- BMI  $\geq 40$  kg/m<sup>2</sup> with one serious comorbidity (such as diabetes mellitus, obstructive sleep apnea, severe or complicated hypertension, or pseudotumor cerebri)

OR

- BMI  $\geq 50$  kg/m<sup>2</sup> with less serious comorbidities
- Failure of non-surgical treatments for obesity
- Adolescents with lower BMI and life-threatening comorbidities should be considered for WLS on a case-by-case basis (Category D).

Exclusion criteria:

- Patient has not attained Tanner stage IV (Category D)
- Patient has not attained 95% of adult height based on estimates from bone age (Category D)
- Female adolescents who are pregnant, breast feeding, or plan to become pregnant within two years of surgery (Category D).

#### **2. Eligibility Evaluations**

WLS requires comprehensive evaluation of the prospective patient and his or her family.

- Knowledge, motivation, and compliance should be assessed by interview and written examination of the adolescent and at least one parent or legal guardian; exam content should evaluate understanding of the planned procedure, the potential risks and benefits, the nature of the potential complications, and responsibility for self-care (Category D).

- Psychological maturity should be evaluated to determine if the patient is able to understand the consequences of WLS, provide informed consent, and comply with medical care and lifestyle changes required prior to and after surgery (Category D)
- Psychological factors that present a contraindication to WLS or that could interfere with treatment, such as eating and/or mood disorders, psychosis, borderline personality disorder, sexual or physical abuse, cigarette smoking, substance abuse and post traumatic stress disorder (PTSD) should be evaluated and treated as appropriate (Category D)
- Eligibility evaluations should include a workup for syndromic or genetic obesity (e.g. Prader Willi syndrome) for candidates suspected of these syndromes and careful consideration on a case-by-case basis to proceeding with surgery in case of a diagnosis of syndromic or genetic obesity (Category D).

### **3. Required counseling**

Female adolescents who undergo WLS must be counseled on the need to postpone pregnancy until at least 2 years after surgery to avoid potential birth defects from nutrient deficiencies. Family planning, including methods of contraception, should be offered to fertile female patients (Category D).

### **4. Recommended procedures**

The limited available data indicate that Roux-en-Y Gastric Bypass (RYGB) and laparoscopic adjustable gastric banding (LAGB) are generally safe and produce durable weight loss when used in adolescents (Evidence is from eight Category C studies, and large-scale adult case series reports).

The Expert Panel recognizes RYGB as the procedure with the best long-term data and LAGB as the procedure with the least apparent risk for adolescent patients. More aggressive (e.g., malabsorptive) procedures should be viewed with great caution in this population (Category C).

Because there are currently no criteria to determine which of the two procedures (RYGB or LAGB) is better for any given patient, the decision should rest with the patient and his or her parents or guardians upon recommendation of the WLS surgeon and other members of the WLS clinical care team.

## **B. Strategies for Medical Error Reduction**

We recommend a peer review process for all programs offering WLS to adolescents every two years. It should be designed to ensure:

- Establishment and maintenance of the high standards of care outlined in this report
- Ongoing collaborative discussion, sharing of techniques, and updating of standards among all programs.

The peer review team should include representation from pediatric specialists in obesity medicine, weight loss surgeons, nutritionists, and mental health providers. Members should be drawn from two or more centers outside the institution under review (Category D). Although this peer review process has not been recommended for programs that provide WLS exclusively to adults, it is recommended here because of the extreme caution needed in developing weight loss programs in this special risk population. There is a paucity of data about WLS in adolescents and the long-term effect of these interventions on psychological and physical development and health.

## **C. Credentialing for Systems and Practitioners**

### **1. Programs**

Credentialing processes for WLS programs, surgeons and other providers should follow the guidelines recommended for the care of adult patients undergoing WLS. Programs providing WLS for adolescents should demonstrate the capacity to comply with the best practice guidelines recommended by the Expert Panel, participate in the peer review process, and collect long-term data.

Programs must modify their physical plant and equipment to accommodate adolescents with severe obesity (Category D, see Facility and QA/QI Resources recommendations).

### **2. Surgeons**

Pediatric surgeons should be eligible for credentialing in WLS using the same criteria as weight loss surgeons for adult patients (see Surgical Care criteria).

Likewise, surgeons providing WLS to adults should be eligible for credentialing to operate on pediatric patients who meet the criteria for WLS (Category D).

## **D. Research Needs for the Future**

### **1. Data collection**

Data collection is essential for improving patient safety and conducting medical research on WLS. Thus, all programs offering WLS to adolescents should be vigorously engaged in collecting short- and long-term data on their adolescent patients.

Databases combining adolescent with adult patients are recommended (see Data Collection /Registry section) (Category D).

### **2. Follow up**

To examine the efficacy and complications of various WLS procedures—especially the newer, less invasive procedures such as LABG—we recommend long-term follow up of adolescent patients.

## **VII. FACILITY AND QUALITY ASSURANCE AND QUALITY IMPROVEMENT (QA/QI) RESOURCES**

There were scant data on facility resources, all purely descriptive. A search of multiple databases identified 14 relevant papers. We also queried several websites, including those of the Agency for Healthcare Research and Quality (AHRQ) and the American College of Surgeons (ACS). All evidence is Category D, unless noted otherwise.

### **A. Patient Safety**

#### **1. Personnel**

We recommend that all medical staff be adequately trained and credentialed in accordance with recommendations from the surgical care, anesthesia perioperative care, and nursing perioperative care task groups.

A team of designated medical subspecialists, fully aware of the problems and sensitivities of patients with severe obesity, should be readily available.

A dedicated hospital administrator should be identified to provide consistent support and oversight. All personnel who interact with WLS patients should attend educational programs focused on the care of patients with severe obesity that include sensitivity training.

#### **2. Equipment**

##### **Operating rooms**

A specially-equipped operating room and ancillary equipment should be available to accommodate patients with severe obesity. Equipment should include:

- An automated extra-wide operating table with appropriate weight capacity
- Extra-long abdominal instrument sets
- Appropriately sized retractors
- 43-46 cm laparoscopes.

Other equipment should include:

- Wide wheelchairs, stretchers, and walkers
- Wide BP cuffs, biphasic defibrillators, sequential compression devices, and emergency airway equipment
- Wide examination tables bolted to the floor
- Scales of appropriate-size and capacity.

##### **Special diagnostic and interventional equipment**



Special diagnostic and interventional equipment is required to accommodate WLS patients, including: appropriate X-ray and ultrasound, CT, MRI, fluoroscopy, interventional facilities, and longer needles.

### **3. Physical Plant**

#### **Post Anesthesia and ICU**

Dedicated beds and specially trained personnel should be available in both the Post-Anesthesia and Intensive Care Units.

#### **Relief staff**

A minimum of two designated floor units are required to provide assigned nurses and attendants intermittent relief from exceptional demands required for the care of patients with severe obesity.

#### **Specially-equipped patient rooms**

Rooms must have sufficiently wide entrances and bathroom doors, and bathroom facilities must have floor-mounted toilets and wide shower stalls.

#### **Patient transport**

Patient transport elevators must have sufficiently wide doors and weight capacity to accommodate patients with severe obesity.

### **B. Strategies for Medical Error Reduction**

#### **Blame-free culture**

We recommend three initiatives to establish a blame-free environment conducive to reporting of adverse events:

- Executive walk-rounds, encouraging communication between executives with decision-making authority and frontline caregivers
- A sentinel event reporting system, enabling and encouraging staff to let the designated hospital administrator and risk manager know about concerns
- A web-based incident reporting system to provide a fast and easy way to report actionable information.

#### **Dedicated pharmacy committee**

An institutional Pharmacy & Therapeutics Committee must be empowered to establish and disseminate appropriate weight-based dosing of drugs commonly used during and after WLS including:

- Analgesics
- Epidural regimens
- Patient-controlled analgesia
- Anxiolytics
- DVT prophylaxis (low molecular weight heparin).

## **Tracking and management**

Effective tracking and management of medication dispensing and administration requires the following equipment:

- Computerized order entry with decision support
- Automated medication dispensing devices
- Electronic medication administration that incorporates bar-code technology (Categories A, B, and C).

## **C. Systems Improvements**

### **Personnel**

Strategies to implement and monitor systems improvements must include the appointment of a Medical Director of the WLS Program to work closely with the designated Hospital Administrator.

### **Information**

A statewide risk-adjusted WLS Data Registry needs to be established and maintained in an accessible outcome tracking system (see Data Collection/Registries Section).

### **Quality Assurance**

- Critical pathways should be developed, implemented, and monitored for adherence; and
- A quality assurance (QA) program specific to WLS should be established.

## **D. Credentialing Needs**

Establish a subcommittee of the Medical Staff Credentials Committee to develop criteria for staff seeking credentialing for emerging technologies.

## **E. Future Research**

### **Collaboration**

- Initiate a collaborative effort with third-party payers to standardize outcome criteria and databases in concert with the recommended statewide registry (also see Data Collection/Registry recommendations)

- Encourage efforts to collaborate with industry on the development of equipment to meet the unique needs of patients with severe obesity; one of the most urgent needs is for imaging equipment that is able to accommodate the increased size and weight of these patients.

## **Training**

Expand simulation training to include situations unique to WLS patients, such as:

- Intravascular line insertion techniques
- Complex airway management
- Response to cardiorespiratory catastrophes
- Techniques for moving WLS patients.

## VIII. CODING AND REIMBURSEMENT

Seventy-six publications were identified in the literature search, and 28 were found to be relevant to the issues of coding and reimbursement; none, however, dealt directly with coding or reimbursement policy issues. We searched the internet and trade press and found substantial additional information relevant to these issues. The Massachusetts Dietetics Association provided information about reimbursement for medical nutrition therapy. All supporting evidence falls under Category D.

### A. Recommendations

#### 1. Align reimbursement policies with clinical objectives

Reimbursement policies should reflect the importance of comprehensive, multidisciplinary care—from preoperative evaluation to long-term monitoring and support. Best practices should be identified for all aspects of care, as well as overall program design. Quality-based premium reimbursement is advisable once reliable, risk-adjusted outcome data become widely available.

##### **Specific steps:**

**Advocate full coverage for multidisciplinary care:** The Expert Panel recommends full insurance coverage for each of the recommended medical, nutritional, and psychological components of the care of patients evaluated for or undergoing WLS.

We recommend that moderate or severe obesity ( $\text{BMI} \geq 35 \text{ kg/m}^2$ ) be qualifying diagnoses for insurance coverage of each of the components of care provided for these patients. Doing so will more accurately reflect the basis for care and allow for improved tracking of obesity and its medical complications in billing databases.

#### 2. Update Current Procedural Terminology (CPT) codes for WLS and related clinical services

Because billing databases are an essential source of activity and outcomes data used to promote patient safety, we recommend that additional CPT codes be established to permit more accurate characterization and tracking of WLS-related clinical services.

The panel recommends that each major category (e.g., gastric bypass, gastric banding, biliopancreatic diversion) of WLS should have a specific CPT code and that laparoscopic approaches to each procedure should be differentially coded from the open versions. These codes should not be used for procedures unrelated to obesity or weight loss. Revisions and conversions from one operation to another should each be coded separately, and a special CPT code should be established for emerging WLS technologies pending determination of the need for establishment of a new procedure-specific code.

##### **Specific steps:**

#### **a. Add new WLS procedures to national CPT codes**

We recommend that the DPH advocate for the addition of national CPT codes for the procedures listed below, and endorse the efforts of other professional, patient advocacy and regulatory bodies that do likewise:

- (a) Laparoscopic adjustable gastric band placement
- (b) Adjustment of gastric band via subcutaneous port
- (c) Open procedure to revise or reverse any type of WLS
- (d) Laparoscopic procedure to revise or reverse any type of WLS
- (e) Open procedure to convert one type of WLS to any other type
- (f) Laparoscopic procedure to convert one type of WLS to any other type

We also recommend that the DPH advocate for the revision of CPT code 43846 (used for “standard” RYGB) to define a short limb as < 150 cm, which would bring this code into line with the CPT codes for laparoscopic RYGB that will be established in January 2005.

#### **b. Establish appropriate CPT codes for each component of WLS care**

We recommend that the DPH advocate for the establishment of specific CPT codes for the multidisciplinary care of patients with moderate or severe obesity evaluated for or undergoing WLS, including:

- Nutritional evaluation
- Medical nutrition therapy, as part of a comprehensive program of therapy for obesity
- Mental health evaluation
- Psychotherapy, as part of a comprehensive program of therapy for obesity
- Physical activity counseling, as part of a comprehensive program of therapy for obesity
- Multidisciplinary team discussions (without the patient present)

### **3. Standardize data collection, tracking, and reporting requirements**

We recommend (a) standardized data collection, tracking, and reporting for all components of multidisciplinary care; and (b) systematic and uniform implementation of data collection and reporting standards by all centers providing WLS (also see Data Collection/Registry recommendations).

This approach is essential to optimize patient safety and promote access to high quality care. We propose a tiered data collection system to meet the diverse needs of various WLS centers and insurers:

- Level 1 data – *standardized* data collection and reporting systems required of all participating centers

- Level 2 data – *standardized* data collection systems used at the discretion of individual centers
- Level 3 data – center, program or provider-specific data collection (not standardized)

#### **Specific steps:**

Data elements to be included within level 1, and perhaps level 2, will need to be defined through a broad-based consensus process. This process could be coordinated by an ongoing advisory committee to the Department of Public Health (also see Data Collection/Registry recommendations). Timely, accurate, and reliable data collection is required for patient safety. Toward that end, we recommend that adequate financial support for data collection and analysis be made available to programs and centers as part of standard reimbursement models for WLS.

#### **4. Give careful consideration to global fees**

Global fees are being implemented for a variety of complex or comprehensive models of clinical activity. We recommend that consideration be given to the use of global fees that encompass the full range of longitudinal care for WLS patients. Reimbursement models for other, well-established models of multidisciplinary care (e.g., organ transplantation, cancer) should be examined and adapted, as appropriate, to the surgical treatment of obesity. The organization of facilities and programs for these other examples of multidisciplinary care may also be relevant for WLS.

#### **Specific steps:**

##### **a. Establish an ongoing advisory committee**

Specific procedures, approaches, and therapies are likely to change rapidly over the next several years. Models of comprehensive, multidisciplinary WLS care are likely to be affected by ongoing developments in laparoscopic, endoscopic, luminal, transcutaneous, and pharmacological therapies, as well as multimodality and combination therapies. Organization of care, reimbursement strategies, and coding practices will need to be quickly adapted to such changes.

We recommend that the DPH establish an ongoing committee to examine and advise the Lehman Center about the effect of reimbursement policies and the impact of emerging technologies for the treatment of moderate and severe obesity in promoting patient safety. This committee should include providers from all relevant disciplines, representatives from WLS facilities, insurers, and the public (also see Data Collection/Registry recommendations)

#### **B. Strategies for Medical Error Reduction**

Consistent, accurate, and timely reporting of outcomes data will help identify patterns of adverse events as well as best practices. It will facilitate refinement of clinical practice, and development of coding and reimbursement policies that promote safe, high-quality patient care.

### **C. Systems Improvement Strategies**

Collaboration among the many professional and trade organizations involved in the care of WLS patients is recommended. Working alone, and together, these groups can identify best practices; develop, evaluate and improve standards of care; and identify and implement increasingly accurate and relevant strategies for outcomes assessment and systems improvements.

### **D. Credentialing Needs**

We recommend that credentialing standards analogous to those recommended for weight loss surgeons be established for all providers in the multidisciplinary WLS care team. Data from specific service and procedure codes will facilitate the identification of appropriate standards for training and experience. These standards can be implemented through provider-specific credentialing and/or institution- or program-based certification.

### **E. Research for Future Needs**

We recommend investigation in the following areas:

- Comparative cost-effectiveness analysis of different WLS procedures
- Identification and validation of outcome predictors for different types of weight loss operations
- The effect of reimbursement policies on the organization and quality of surgical therapies for obesity
- The effect of reimbursement policies, including reimbursement for multidisciplinary care and premium payments for demonstrated quality, on economic outcomes and cost-benefit relationships
- The effect of reimbursement policies on regional, cultural, and socioeconomic variation in utilization and outcomes
- The effect of different co-payment models on utilization, clinical outcomes, and patient satisfaction
- The impact of different models of multidisciplinary care on clinical and economic outcomes.

## **IX. Data Collection (Registries) / Future Considerations**

We identified over 150 publications in our literature search; 16 of these were reviewed in detail. There were few if any studies on the affect of data registries on the care of WLS patients. To compensate for the lack of data, we broadened our search to include databases from related fields (such as cardiac and thoracic surgery), as well as cancer data registries. Recommendations are based on available evidence as well as consensus of opinions from task group and expert panel members.

### **A. Patient Safety Recommendations**

#### **Evidence**

No research has been conducted on whether a system for collecting data on WLS improves patient safety and outcomes. Related evidence, especially from the field of cardiac surgery, suggests that regional or national risk-adjusted data collection systems may improve patient safety and decrease surgical mortality rates (Categories B and C).

#### **Current status**

There is no standardized data collection system or registry for WLS in Massachusetts (or any other state) at this time. Cardiac surgery is the only surgical field in which data collection is mandatory. Rapid growth in WLS has created a compelling need for a sophisticated yet accessible database.

NIH, working with six clinical centers and a data coordinating center, has recently established the Longitudinal Assessment of Bariatric Surgery (LABS) to plan, develop, and conduct coordinated clinical, epidemiological, and behavioral research in WLS through the development of common clinical protocols and a WLS database. The goal of LABS is to standardize definitions and data collection instruments across different centers and to study the risks and benefits of different WLS procedures. LABS could serve as a model for statewide WLS registry.

#### **Rationale**

WLS patients have unique risks and needs. Data are required to evaluate efficacy of treatments and monitor outcomes. Other considerations:

- WLS is a high-risk procedure performed in high-risk patients, but these risks are not fully characterized
- Risk may be higher than expected; a recent study suggests that the population-based mortality rate from WLS is four times higher than reported in single institution studies
- There is rapid growth in demand; the number of gastric bypass operations in Massachusetts alone climbed from 402 in 1998 to 2761 in 2003, an increase of nearly 600% in five years



- Novel approaches and technologies, such as LAGB and laparoscopic gastric bypass, need to be monitored for safety and efficacy; intraluminal or endoscopic techniques are likely to be introduced in the near future
- Public concern about the safety of these procedures is intense; demand for accurate and current information comes from multiple sources, including patients, surgeons, researchers, insurers, HMOs, hospital administrators, risk management companies, and regulatory commissions.

## **Recommendation**

The Expert Panel recommends that the Betsy Lehman Center establish a committee (membership on this committee to include the Board of Registration in Medicine) to advise the Department of Public Health on the development of a statewide data collection system for all programs, centers and institutions that perform WLS (see also Coding and Reimbursement recommendations).

## **System description**

The system should be:

- Confidential
- Prospective
- Risk-adjusted
- Multicenter
- Benchmarked
- Based on standard definitions of data points.

Data should be collected by a sophisticated, trained, unbiased, and audited reviewer.

## **Appropriate Data**

Preoperative, intraoperative, postoperative, and long-term follow up data are appropriate for collection (also see a tiered system recommended by Coding and Reimbursement Task Group).

## **B. Research Needed for the Future**

The Expert Panel believes that a mandatory statewide data collection system for WLS programs would promote continuous quality improvement and enhance patient safety. The development of such a system, however, is a formidable task.

To address challenges, we recommend:

- A committee to examine such issues as standardization of a data collection system; the possibility of a tiered system (see Coding and Reimbursement recommendations); and a combined adolescent/adult database (also see Pediatric/Adolescent recommendations)

- A pilot study to beta test any proposed system
- A feasibility study to address not only the complexities of such a system, but also the financial impact on those involved.

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# Appendix I

## Framework and Methodology for Evidence-Based Systematic Reviews of Literature on Weight Loss Surgery

The Expert Panel was charged with reviewing WLS operations, identifying potential safety issues, and recommending specific actions to reduce safety risks and improve patient outcomes. It used the methodology of evidence-based medicine to systematically search available literature on the subject, and developed a classification system from established models to grade the quality of evidence.

The systematic review involved a MEDLINE search of studies published from January 1980 to April 2004. These included prior systematic reviews on the subject; randomized controlled trials; prospective cohort studies; cross-sectional surveys; case reports; and existing guidelines on WLS procedures from national organizations. The panel based its grading classification system on those used by the U.S. Preventive Services Task Force, the American Diabetes Association, and the National Heart, Lung, and Blood Institute (NHLBI) Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.

Randomized controlled trials (RCTs) are considered the highest-level evidence of clinical efficacy and safety, but there are few such studies on WLS operations. The panel's recommendations are based on the best available evidence—observational studies and expert opinions. The sections below detail the procedures and methodology used to develop recommendations.

### 1. Panel Selection

At the request of Massachusetts Public Health Commissioner Christine Ferguson, the Betsy Lehman Center for Patient Safety and Medical Error Reduction (Lehman Center) convened an Expert Panel to study patient-related safety issues in the state's WLS programs and procedures.

The 24-member panel includes: experienced weight loss surgeons; nurses, a psychologist, and a nutritionist who counsel patients before and after the procedures; other physicians who care for patients with obesity (an anesthesiologist, internist, and pediatrician); a hospital patient safety officer; a health plan medical director; an ethicist; and a consumer. The panel delivered a report on its progress to the Lehman Center and the Department of Public Health in late May.

### 2. Task Groups

We divided the panel into nine task groups:

- Multidisciplinary (medical, nutritional, psychological) evaluation and treatment and criteria for patient selection;
- Patient education/informed consent;

- Surgical care;
- Anesthetic perioperative care and pain management;
- Nursing perioperative care;
- Pediatric/adolescent care;
- Data collection (registries)/future considerations;
- Facility and quality assurance/quality improvement (QA/QI) resources; and
- Coding and reimbursement.

Panel members joined one or two task groups, each with an assigned coordinator. While developing recommendations, they were asked to focus on five topics: patient safety; medical errors; credentialing of systems and practitioners; systems improvements; and research needed for the future.

### **3. Literature Search**

An expert in library science, aided by a clinical epidemiologist with experience in systematic reviews, carried out literature searches for each task group. Studies were included or excluded based on *a priori* criteria, i.e., written protocols that defined research questions, and search parameters, including patient characteristics, study designs, surgical interventions, and outcomes.

MEDLINE searches were limited to English-language studies published from January 1980 to April 2004 (Some groups have searched other databases or focused on more recent literature). References in retrieved articles, guidelines from national organizations, and systematic reviews from the Cochrane Library were also examined. Task group coordinators, with input from the clinical epidemiologist, screened all titles and abstracts; they selected only those most relevant to the review questions.

The literature searches focused on commonly performed procedures (e.g., Roux-en-Y gastric bypass, vertical banded gastroplasty, gastric banding, and biliopancreatic diversion). Data on other types of surgeries were very limited, or irrelevant. Some procedures are no longer performed.

### **4. Data Extraction and Tabulation**

The panel developed a data extraction sheet, and used it to pull detailed information from selected full articles after review. Key data included study design; size; patient demographics; follow up time; drop-out rate; description of the intervention; outcome measures, including adverse effects; and main conclusions. Information was tabulated in a format suitable for publication.

### **5. Synthesis of Evidence**

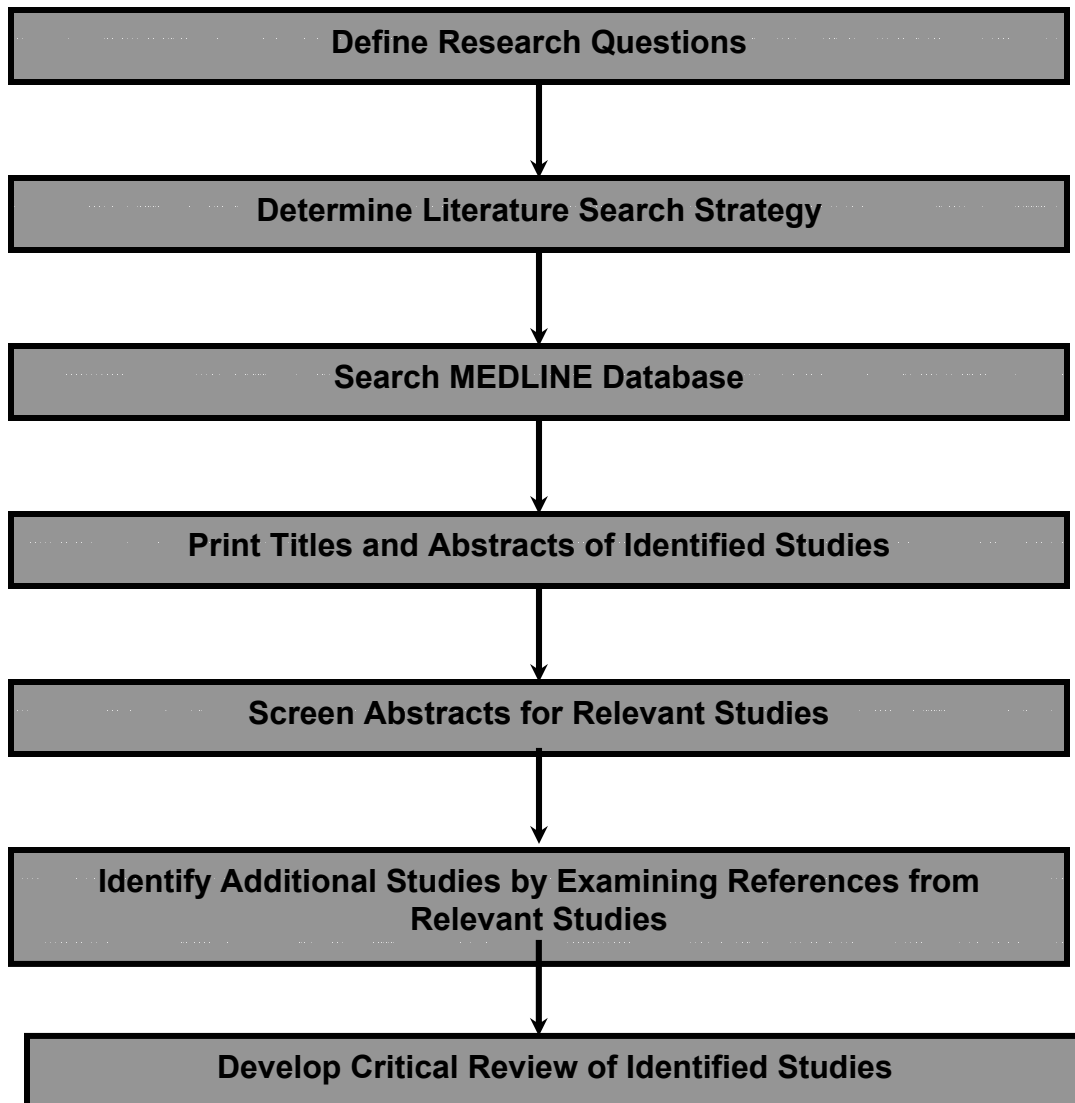
Narrative (or qualitative) summaries were primarily used for the literature review because study designs and outcomes are too dissimilar to combine results in a formal meta-analysis. All selected studies were critically assessed for internal validity or methodological rigor. They were ranked according to levels of evidence based on study design (see Table 1). For example, well-

conducted RCTs (Category A evidence) provide the strongest evidence on the effectiveness of a surgical weight loss procedure. Expert opinion (Category D evidence) including clinical experience, the opinions of respected authorities, reports from expert committees, consensus of the Expert Panel was used in conjunction with evidence from RCTs or observational studies to develop recommendation.

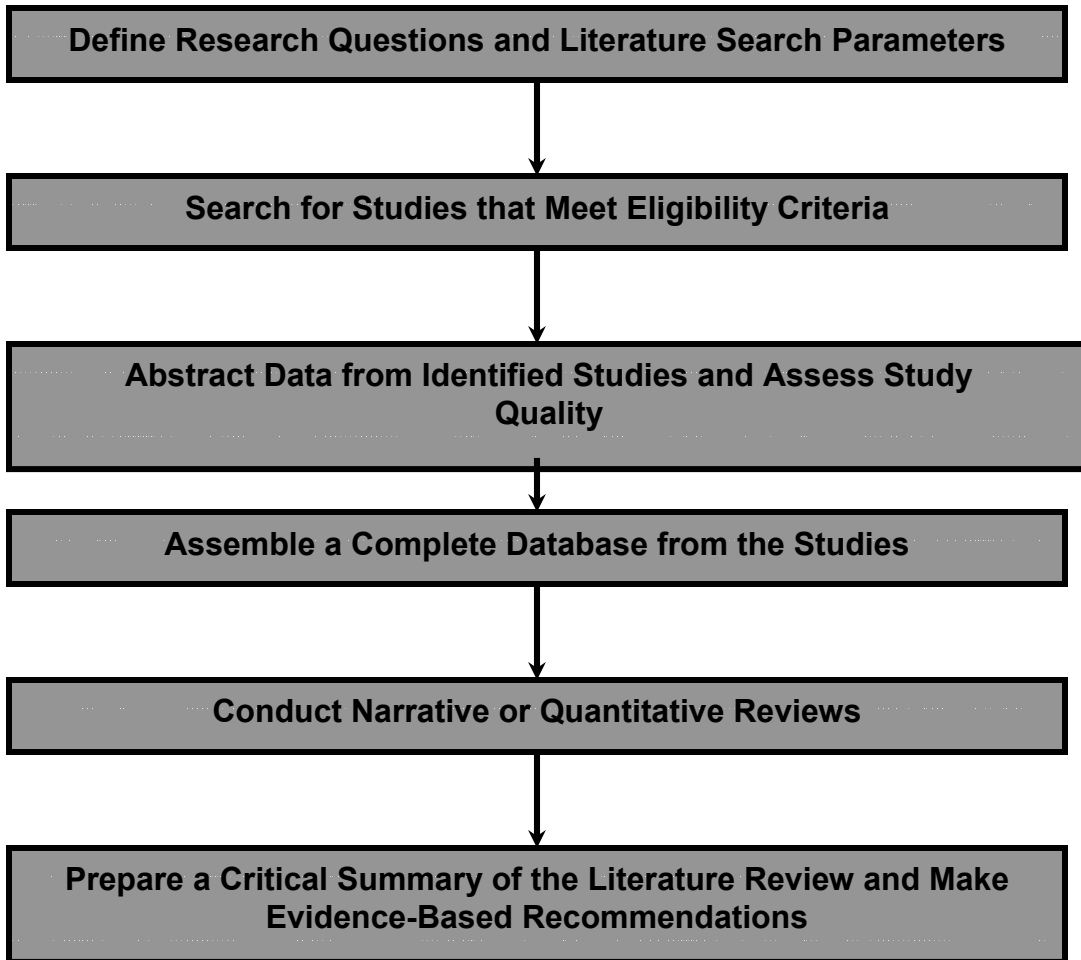
## **6. Developing Evidence-Based Recommendations**

Each task group prepared a critical summary of the literature and developed evidence-based recommendations on its assigned topic, which were presented to the full group for comments. This Executive Report of key recommendations from all groups was approved by the full panel at the last meeting on July 19, 2004.

## Literature Search Process



## Literature Review Process



**Table 1. Grading System for Evidence-Based Recommendations**

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Category A	Evidence obtained from at least one well-conducted randomized clinical trial or a systematic review of all relevant RCTs
Category B	Evidence from well-conducted prospective cohort studies, registry or meta-analysis of cohort studies, or population-based case-control studies
Category C	Evidence obtained from uncontrolled or poorly controlled clinical trials, or retrospective case-control analyses, cross-sectional studies, case series, or case reports
Category D	Evidence consisting of opinion from expert panels or the clinical experience of acknowledged authorities

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Adapted from the criteria used by the U.S. Preventive Services Task Force (USPSTF) and the American Diabetes Association.

**Table 2. Inclusion/Exclusion Criteria – Example Used in Literature Search, Laparoscopic vs. Open Gastric Bypass Surgery**

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Inclusion criteria

- English language
- Published between January 1980 and April 2004
- RCTs or controlled trials without randomization, cohort studies
- Surgical procedures: gastric bypass, Roux-en-Y gastric bypass, open vs. laparoscopic
- Minimum follow up: 6 months
- Outcomes: change in body weight, excess weight, and BMI; mortality and major morbidity

Exclusion criteria

- Selection criteria not indicated
  - Small sample size ( $n < 10$  for each intervention)
  - Drop-out rate  $> 50\%$
-

## References for the Framework

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## Appendix II

### **DATA EXTRACTION SHEET**

**First Author:**

**Title:**

**Source:**

**Date of Study:**

**Study Location (*geographical*):**

**Study Design (*Check One*):**

- ☐ Systematic Review/Meta-Analysis
- ☐ Randomized Clinical Trial
- ☐ Non-randomized Clinical Trial
- ☐ Cohort Study
- ☐ Case Series or Report

**\*\*\* If the study is a systematic review or meta-analysis, you can directly to Major Conclusions and Clinical Implications at the end of this sheet.**

**Inclusion/Exclusion Criteria (list):**

Inclusion-

Exclusion-

**Sample Size:**

*Number in each arm of trial* \_\_\_\_\_

**Patient Characteristics:**

*Age Range* \_\_\_\_\_  
*Gender* \_\_\_\_\_  
*Medical Conditions* \_\_\_\_\_  
*Initial Body Weight* \_\_\_\_\_  
*Initial BMI* \_\_\_\_\_

**Intervention Details:**

*Care Setting-*

*Treatment Group-*

**Comparison Group-**

*Duration of intervention-*

**Who delivered intervention-**

**Outcome measures:**

*What were they?*

*Methods of assessing outcome measures-*

**Statistical Analysis:**

*Baseline Comparability-*

*Statistical Adjustment for confounding-*

*Subgroups considered-*

**Major Conclusions:**

**Clinical Implications:**

Overall quality grading-

# Appendix III

## Task Groups for Lehman Center Report on Weight Loss Surgery

### **Multidisciplinary Evaluation and Treatment (Medical, Nutritional, Psychological) AND Criteria for Patient Selection**

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Beth Israel Deaconess Medical Center

Lorrie Young, R.N., M.S., C.N.S.D.  
Boston University Medical Center

### **Patient Education/Informed Consent**

Jim Sabin, M.D., Coordinator  
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Robert Fanelli, M.D.  
Berkshire Medical Center

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Consumer

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## GLOSSARY

<b>ACGME</b>	American Council for the Accreditation of Graduate Medical Education. An accrediting agency composed of representatives from five national associations interested in graduate medical education in addition to a federal government representative, three public representatives chosen by the ACGME, and a resident physician representative. The ACGME, through its 27 review committees (26 Residency Review Committees, or RRC, and the Traditional Year Review Committee), accredits graduate medical education programs.
<b>Analgesics</b>	Compounds capable of relieving pain without the loss of consciousness or without producing anesthesia.
<b>Anesthetics</b>	Drugs that are capable of inducing a total or partial loss of sensation, especially pain. They may act to induce general anesthesia, in which an unconscious state is achieved, or may act locally to induce numbness or lack of sensation at a targeted site.
<b>Ascites</b>	Accumulation or retention of fluid within the abdominal cavity.
<b>Bariatric</b>	Adjective from the Greek words for weight and treatment, bariatric means related to weight loss.
<b>Beta Blockers/Adrenergic Beta-Antagonists</b>	Drugs that are used for treatment of high blood pressure, heart arrhythmias, angina pectoris, glaucoma, migraine headaches, and anxiety. They work by blocking beta receptors causing a decrease in heart rate and of heart contractions causing a decrease in blood pressure.
<b>Biliopancreatic Diversion</b>	A weight loss surgery where portions of the stomach are removed. The small pouch that remains is connected directly to the last segment of the small intestine, thus completely bypassing both the duodenum and jejunum. Although this procedure successfully promotes weight loss, it is not widely used because of the high risk for nutritional deficiencies.
<b>Biphasic Defibrillator</b>	Electrical device used to restore the normal rhythm to a heart that is beating irregularly.
<b>BMI</b>	Body mass index. A measure of body mass. A formula (weight in kilograms divided by height in meters squared) for standardizing the extent of overweight.
<b>Borderline Personality Disorder</b>	A personality disorder marked by a pattern of instability in interpersonal relationships, self-image, feelings, and marked impulsivity beginning by early adulthood.
<b>BUN</b>	Blood Urea Nitrogen (BUN) is the concentration of nitrogen in the form of urea in the blood.
<b>Bupropion</b>	A drug used as an antidepressant and as an aid to stop smoking usually without the side effects of decreased sex drive and weight gain.
<b>Case-Control Studies</b>	Studies which start with the identification of persons with a disease of interest

	and a control group without the disease. The relationship of an attribute to the disease is examined by comparing diseased and non-diseased persons with regard to the frequency or levels of the attribute in each group.
<b>Cirrhosis</b>	Widespread disruption of normal liver structure by fibrous tissue seen in chronic progressive conditions affecting the liver.
<b>Cohort Studies</b>	Studies in which subsets of a defined population are identified. Cohorts are defined populations which, as a whole, are followed in an attempt to determine distinguishing subgroup characteristics.
<b>Coronary Disease</b>	An imbalance between heart muscle requirements and the capacity of the coronary (heart) vessels to supply sufficient blood flow.
<b>CPAP/BiPAP</b>	Continuous and bi-level positive airway pressure. Methods of facilitating ventilation and preventing upper airway collapse during sleep and sedation by using a tight fitting face mask connected to a machine. Often used at night in patients with sleep apnea.
<b>Clinical Pathways</b>	Schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment.
<b>Creatine</b>	An amino acid that occurs in tissues and in urine. In muscle tissue, creatine generally occurs as phosphocreatine. Creatine is excreted as Creatinine in the urine.
<b>Current Procedural Terminology</b>	Descriptive terms and identifying codes for reporting medical services and procedures performed by physicians. It is produced by the American Medical Association (AMA) and used in insurance claim reporting for Medicare, Medicaid, and private health insurance programs.
<b>Deep Vein Thrombosis</b>	The formation or presence of a thrombus or clot within a vein.
<b>Dumping Syndrome</b>	When stomach contents move too rapidly through the small intestine. Symptoms include nausea, weakness, sweating, faintness, and occasionally, diarrhea after eating. There also may be the inability to eat sweets without becoming so weak and sweaty that the patient may have to lie down until the symptoms pass.
<b>Dyslipidemia/Hyperlipidemia</b>	An excess of lipids (fats) in the blood.
<b>Endotracheal intubation</b>	Introduction of a tube into the trachea to provide an open airway to administer oxygen, gaseous medication, or anesthetics. May also be done to remove blockages, or to view the inside walls of the trachea.
<b>Ephinephrine</b>	The active hormone from the adrenal glands (located upon the kidneys) that causes systemic constriction of the blood vessels, gastrointestinal relaxation, stimulation of the heart, and opening of the bronchi and cerebral vessels. It is used in asthma and heart failure and to delay absorption of local anesthetics.
<b>Esophagitis</b>	Inflammation of the esophagus caused by bacteria, chemicals, or trauma.



<b>Gastric Banding</b>	A band made of special material that is placed around the stomach near its upper end, creating a small pouch of the upper stomach and a narrow passage into the larger remainder of the stomach.
<b>Gastric Bypass</b>	Surgical procedure used frequently in the treatment of morbid obesity. A small section of the upper stomach is stapled off from the rest of the stomach. Then this small stomach is connected to part of the small intestines (jejunum).
<b>Gastroesophageal Reflux</b>	Flow of gastric juice (gastric acid) and/or duodenal contents (bile acids, pancreatic juice) into the esophagus, commonly due to a faulty lower esophageal sphincter (band of muscle) and/or presence of a hiatal hernia. "Heartburn" is the symptom associated with this.
<b>Glucose Intolerance</b>	A disease in which blood glucose level is less than approximately 140mg/100ml of plasma after fasting, and above approximately 200mg/100ml plasma at 30-,60-,or 90-minute intervals during a glucose tolerance test. This condition is seen frequently in diabetes mellitus, but also occurs with other diseases and malnutrition.
<b>Hernia</b>	The protrusion of abdominal contents through a weakness or defect in the abdominal wall. Ten to twenty percent of patients who have the open weight-loss surgery may develop a hernia in the incision.
<b>Hematocrit</b>	The volume of packed red blood cells in a blood specimen.
<b>Insulin Resistance</b>	Decreased effectiveness of insulin in lowering blood sugar levels. It is associated with obesity.
<b>Jejunioileal Bypass</b>	A surgical procedure, no longer performed today, that was used to treat extreme obesity. The first part of the jejunum was connected to the last portion of the ileum, so as to bypass the area of the intestine where nutrients are absorbed.
<b>Laparoscope</b>	Thin fiber-optic surgical scope used to view and examine internal organs that is introduced into the body through a small incision.
<b>Laparoscopic</b>	Abbreviated "Lap." Operation performed using a laparoscope and other small surgical instruments that fit through small incisions.
<b>Laparoscopic Adjustable Gastric Banding (LAGB)</b>	In LAGB, an adjustable silicone band is placed around the upper stomach to create a small pouch and a restricted outlet to the rest of the stomach. The diameter of the outlet can be changed by injecting or removing saline (salt water) through an opening (port) under the skin. If necessary, the band can be removed. Though a large body of evidence, especially from European studies, suggests that LAGB is effective and safe for weight loss, long-term data are still limited in the U.S. Complications from gastric banding include band movement or erosion, gastroesophageal reflux disease (GERD), esophagitis, and port or tubing problems.
<b>Laparoscopic WLS</b>	Like open gastric restrictive procedures, laparoscopic WLS (weight loss surgery) has proven effective at producing significant and sustained weight loss, along with improvements in other medical problems associated with obesity and quality of life. Because it is less traumatic to the body than open

	<p>surgery, it also shortens recovery time.</p> <p>Laparoscopic surgeons gain access to the stomach via several small incisions. They insert a tiny video camera through one of the incisions, and surgical instruments through the others. They operate by watching their work on a large-screen monitor.</p>
<b>Low Molecular Weight Heparin</b>	An effective agent used to prevent blood clots with less risk of hemorrhage (bleeding) than heparin with greater molecular weight.
<b>Medline</b>	Medical Literature, Analysis, and Retrieval System Online is the U.S. National Library of Medicine's (NLM) premier bibliographic database that contains over 12 million references to journal articles in life sciences with a concentration on biomedicine.
<b>Meta-Analysis</b>	A quantitative method of combining the results of independent studies (usually drawn from the published literature) and synthesizing summaries and conclusions which may be used to evaluate therapeutic effectiveness, plan new studies, etc., with application chiefly in the areas of research and medicine.
<b>Micronutrients</b>	Essential dietary elements or organic compounds that are required in only small quantities for normal physiologic (body functions) processes to occur.
<b>Narcotics</b>	Drugs that have potent analgesic (pain reducing) effects associated with significant changes in mood and behavior, and with the potential for dependence and tolerance following repeated administration.
<b>Nicotine Replacement Therapy (NRT)</b>	Administration of nicotine (the active ingredient in tobacco) in different forms (gum, transdermal patch, nasal spray, inhaler, sublingual tablet and lozenge), and has been shown to relieve withdrawal symptoms and to double abstinence (quitting) rates compared to placebo (a substance that looks like a drug, but has no effects) for people trying to quit smoking.
<b>Obstructive Sleep Apnea</b>	A disorder characterized by repeated periods of not breathing during sleep despite repeated efforts to breathe. It is due to upper airway blockage. Frequent periods of waking up occur throughout sleep, resulting in relative sleep deprivation and daytime tiredness.
<b>PCA (Patient-Controlled Analgesia)</b>	Self-administration of analgesics (medication that decreases pain) by a patient instructed in doing so. It usually refers to self-dosing with intravenous opioid (e.g. morphine) administered by means of a programmable pump.
<b>Prader-Willi Syndrome</b>	A chromosomal disorder associated with mental disorder and obesity.
<b>Protein-Energy Malnutrition</b>	The lack of sufficient energy or protein to meet the body's metabolic demands, as a result of either an inadequate dietary intake of protein, intake of poor quality dietary protein, increased demands due to disease, or increased nutrient losses.

<b>Psychotic Disorder</b>	A serious mental disorder in which the mind does not function normally and the ability to deal with reality is impaired or lost.
<b>Pulmonary Embolism</b>	A blood clot or thrombosis from another part of the body (e.g., lung) that travels to the lung with grave consequences.
<b>Randomized Controlled Trials</b>	Clinical trials or tests that involved at least one test treatment and one control treatment, concurrent enrollment and follow-up of the test and control-treated groups, and in which the treatments to be administered are selected by a random process.
<b>Registry</b>	A place where data, records, or laboratory samples are kept and usually made available for research or comparative study.
<b>Roux-en-Y Gastric Bypass</b>	RYGB is the gold standard WLS (weight loss surgery) in the U.S. today, and the most frequently performed. It involves creating a tiny stomach pouch and rerouting a portion of the digestive tract to reduce absorption of food in the intestine. Proven benefits of RYGB include improvement of obesity-related problems and significant long-term weight loss. Its risks include infrequent but serious surgical complications (e.g., staple line failure, PULMONARY EMBOLISM, wound infection, and intestinal leak); long-term deficiencies of vitamin B12, folate, and iron; and weight regain.
<b>Splenectomy</b>	Surgical removal of the spleen.
<b>Stress Disorders, Post-Traumatic</b>	Psychiatric illnesses that are caused by a traumatic event that may be re-experienced by flashbacks, as well as other symptoms, such as arousal, depression, and sleep disturbances.
<b>Tanner Stage</b>	Stages of sexual development that take place during puberty. Tanner Stage IV: females – breast areola and papilla form secondary mound; pubic hair has adult characteristics but not adult distribution; males – testes and scrotum exhibit further penile enlargement and darkening of scrotal skin; pubic hair has adult characteristics but not adult distribution.
<b>The CINAHL Database</b>	Database for nursing and allied health literature.
<b>Thiamine/ Vitamin B</b>	Found in bran, yeast, and meat necessary for carbohydrate metabolism and normal activity of the nervous system.
<b>Thoracic Epidural Analgesia (TEA)</b>	The relief of pain without loss of consciousness through the introduction of a pain reducing drug into the epidural space of the vertebral canal. It is differentiated from epidural anesthesia, which refers to the state of insensitivity to sensation.
<b>Thoracic Surgical Procedures</b>	Surgery performed on the thoracic (chest) organs, most commonly the lungs and the heart.
<b>Transaminases</b>	A subclass of enzymes of the transferase class that catalyze the transfer of an amino group from a donor (generally an amino acid) to an acceptor (generally a 2-keto acid).

<b>Vertical Banded Gastroplasty (VBG)</b>	This procedure is becoming the most frequently used restrictive operation for weight control. Both a band and staples are used to create a small stomach pouch. The procedure works best on individuals who are not binge eaters.
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